IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
(DALLAS DIVISION)

MILLARD ANDERSON and JENNIFER ANDERSON, Individually and as Next Friends of CBA, a Minor, Plaintiffs,	§	
vs.	§	CASE NO. 3:11-cv-01825-L
ABBOTT LABORATORIES, Defendant.	§	

PLAINTIFFS' BRIEF IN SUPPORT OF RESPONSE TO DEFENDANT'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Respectfully submitted,

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Table of Contents

Table of Authorities

Case **Page(s)**

Rules/Statutes **Page(s)**

Other **Page(s)**

For the following reasons, Abbott's Motion to Dismiss Plaintiffs' Complaint is ill-founded in both law and fact and should be denied.

Introduction and Procedural Posture

The undersigned has been representing families in claims against pharmaceutical companies for 15 years. Within the past year, he has filed suit against Abbott with respect to Humira induced injuries in 12 cases. These cases are primarily centered in state court in Abbott's home state of Illinois, however, there are a handful of cases scattered in other federal jurisdictions across the country, to include two in Texas. In the other Texas Humira/cancer personal injury case we are handling, *Murthy v. Abbott Laboratories*, Case No. 4:11-cv-00105-KPE (S.D.TX), Abbott filed a substantially similar motion to dismiss instead of filing an answer. These Humira cases represent the first time that the undersigned has been accused of failing to plead *enough* facts. Even a cursory examination of the Complaint will reveal why the motion is misguided.

Be that as it may, despite the fact that Abbott appears to routinely lose these types of motions, it continues to "swing for the fences" irrespective of the content or thoroughness of the complaint at issue. *See e.g., Mohr v. Targeted Genetics, Inc.*, 690 F.Supp.2d 711 (C.D. Illinois 2007); *Wendell v. Johnson & Johnson*, 2010 WL 2465456 (N.D.Calif. June 14, 2010).[1] Undoubtedly this strategy is the product of a tortured exaggeration of the word "plausible" in *Twombley*[2] and *Iqbal*.[3]

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[1] Although it is not apparent from the case names, both cases involved Abbott and Humira. *Mohr* was a Humira/histoplasmosis case. Abbott was a defendant. The district court rejected both (a) the *Twombly/Iqbal* basis for dismissal, and (b) the alternative "learned intermediary" argument and remanded the case to state court. *Wendell* is even more *a propos*, as it involved allegations of Humira-induced lymphoma. The court there rejected a *Twombly/Iqbal* based motion to dismiss that focused on (a) the adequacy of the Humira label to warn against lymphoma, (b) failure to warn, and (c) causation.

Given that Abbott failed to cite or otherwise attempt to differentiate either *Mohr* or *Wendell* for the court in *Murthy*, it is not terribly surprising they do not bring them to this Court's attention.

[2] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In this 7:2 opinion, the Court sustained the trial judge's dismissal of an antitrust conspiracy complaint that rested on averments

Irrespective, it is important that the Court not allow Abbott, as it has done throughout its Motion, to continue to confuse and intertwine decisions based on post-discovery summary judgment standards and those of Rule 12(b)(6). At this stage of the litigation, Abbott has not filed an Answer nor has any evidentiary record been developed.

Before turning to the substance of our Response, it should be noted that the *rationale* of *Twombly/Iqbal* is not present in this case. The U.S. Supreme Court was quite clear in its opinions that the major rationale of its "plausibility" standard was to avoid the protracted proceedings, annoyance, and associated costs for a case that had almost no hope for success:

> As we indicated over 20 years ago . . . "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." . . . ("[T]he costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint").

Twombly, supra, 550 U.S. at 558 (citations omitted). *Accord Iqbal*, 129 S.Ct. at 1953-54.

Those considerations do not apply, where, as here, numerous plaintiffs, represented by several different law firms have filed several lawsuits in state and federal courts across the country to seek redress from Humira-induced injuries. The *Wendell* case, cited above, and the case of

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of "parallel" conduct rather than objective allegations of unlawful conduct. It did so largely because of the enormous waste of time and resources involved in conducting discovery on a case that did not have a "hope" of success in the long run. Hardly an earthshaker. There is, however, considerable irony in the fact that an opinion which consigned the "no set of facts" language of *Conley v. Gibson,* 355 U.S. 41 (1957) to "retirement" because it had been "puzzling the profession for 50 years", 550 U.S. at 563, has now precipitated more citations than almost any case in the last hundred years, with the possible exceptions of *Erie* and *Daubert*.

[3] *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). This 5:4 opinion held that the facts alleged did not suffice to show a purposeful discrimination by government agents. Significantly, however, the High Court remanded to the Second Circuit to decide whether the plaintiff should be given an opportunity to cure with a Rule 15 amendment, and the Second Circuit then sent it back to the district judge to make that determination. 574 F.3d 820 (2nd Cir. 2009).

Murthy, both involve allegations of Humira-induced lymphoma. As mentioned previously, the undersigned also represents other plaintiffs with Humira induced lymphomas and other cancers. Abbott has already produced nearly 1,100,000 pages of documents, produced for deposition three 30(b)(6) witnesses, with a fourth to take place in the future, and is currently set for trial in January 2012 in yet a different Humira/lymphoma case with the undersigned. Thus, dismissal of this Complaint would not spare Abbott the costs of defending this $8 billion/year drug.

Stated simply, and as detailed further below, Plaintiffs' Complaint alleges enough facts to overcome even the most strained construct of plausibility. Abbott's motion should be denied.

Legal Standard: The "Short Plain - Plausible" Pleading

The legal standards for ruling on a Motion to Dismiss under Rule 12(b)(6) are well known to this Court:

> To defeat a motion to dismiss filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." A claim meets the plausibility standard "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.
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> In reviewing a Rule 12(b)(6) motion, the court must accept all well-pleaded facts in the complaint as true and view them in the light most favorable to the plaintiff.
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> The ultimate question in a Rule 12(b)(6) motion is whether the complaint states a valid claim when it is viewed in the light most favorable to the plaintiff. ... The court does not evaluate the plaintiff's likelihood of success; instead, it only determines whether the plaintiff has pleaded a legally cognizable claim.

Marquez v. Fed. Nat. Mortg. Ass'n, 2011 WL 3714623, 2-3 (N.D. Tex. Aug. 23, 2011)(citations omitted).[4]

We these principles in mind, we now turn to Abbott's arguments.

ARGUMENT AND AUTHORITIES

I. § 82.007 DOES NOT WARRANT DISMISSAL.

A. There is No Basis for Dismissal Under § 82.007. Abbott assumes, without argument, that Texas substantive law governs this case. For purposes of this Motion only, we will assume that this is indeed true. Section 82.007 of the Texas Civil Practices and Remedies Code is a procedural statute. It creates a *rebuttable evidentiary* statutory presumption that a drug manufacturer is not liable for giving warnings or instructions that are pre-approved by the FDA. However, as the only Texas court which analyzed the statute in relative detail held, "once evidence contradicting the presumption has been offered, the presumption disappears and is not weighed or treated as evidence." *Ackermann v. Wyeth Pharmaceuticals*, 471 F. Supp. 2d 739, 749 (E.D. Tex. 2006) aff'd, 526 F.3d 203 (5th Cir. 2008).

In light of that precedent, the procedural posture of this case is important *vis-a-vis* the statute. Procedurally, the Plaintiff must file a Complaint containing a "short and plain statement" that shows that she is "entitled to relief." Rule 8, FED. R. CIV. P. Although the case law is sparse, it is clear that the "general rule" of pleading is that there is no requirement to "anticipate a defense." *See e.g., Gomez v. Toledo,* 446 U.S. 635, 640, (1980)("We see no basis for imposing on the plaintiff an obligation to anticipate such a defense [qualified immunity] by stating in his complaint that the

[4] We apologize for the lengthy quotation from this Court's opinion. However, because it is so recent and because it is a synopsis of the current state of the law in this Circuit regarding motions to dismiss in the wake of *Iqbal* and *Twombly*, it seemed to be the most effective use of the time and space.

defendant acted in bad faith.").[5] Eighteen years later, the High Court reaffirmed *Gomez* and wrote about the perils of judicial decisions that, in effect, "change the Federal Rules governing pleading by requiring the plaintiff to anticipate [the immunity] defense." C*rawford-El v. Britton,* 523 U.S. 574, 595 (1998).[6]

The defendant's Answer "must affirmatively state any . . . affirmative defense." Rule 8(c), FED. R. CIV. P. At this point procedurally, Abbott has not yet filed an Answer in this case. However, pharmaceutical companies typically assert § 82.007 as an affirmative defense, so it is likely that Abbott will do so as well. But it has not done so as of yet.

Section 82.007 (and its parallel § 82.008) specifically provides for a rebuttable *evidentiary presumption*: "there is a rebuttable presumption that . . ." Indeed, the statute even sets forth some[7] of the evidence that might be used to rebut the presumption. And as the court in *Ackermann* held "once *evidence* contradicting the presumption has been offered, the presumption disappears and is not weighed or treated as evidence." 471 F. Supp. 2d at 749. Clearly, dismissing the case at this

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[5] In subsequent § 1983 cases the Fifth Circuit has held that courts can "stand by our insistence that complaints plead more than conclusions, and that a plaintiff can, at the pleading stage, be required to *engage the affirmative defense* of qualified immunity when invoked." *Schultea v. Wood,* 47 F.3d 1427, 1430 (5th Cir. 1995). However, even here, the plaintiff is not required to anticipate the affirmative defense until it has been "invoked" by an answer and the court has decided to require further pleading. *See e.g., Detro v. Roemer,* 732 F. Supp. 673, 675 (E.D. La. 1990)("Because qualified immunity is an affirmative defense which must be pleaded, the plaintiff need not anticipate the defense in his complaint.").

[6] The Texas learned intermediary doctrine is also an affirmative defense and it would be equally premature to dismiss this lawsuit based on an unplead affirmative defense. *See* section II, *infra*.

[7] At this point, the paucity of judicial construction of § 82.007 leaves open the question of whether the list of evidence that could be used to rebut the presumption is *exclusive*, or merely illustrative.

juncture prohibits any opportunity to develop evidence to satisfy the statute and would, in essence, turn the statute into a complete bar on pharmaceutical litigation in Texas.[8]

Further, an examination of Abbott's motion and memorandum reveals no clear dispositive precedent with respect to § 82.007.[9] The closest case that is seemingly on point offered by Abbott is the unreported opinion in *Thurston v. Merck and Co. Inc.,* 415 F. App'x 585 (5th Cir. 2011).[10] *See* Abbott's Amended Memorandum of Law in Support of Defendant's Motion to Dismiss Plaintiffs' Complaints [hereinafter "Abbott's Memo"] at 11, 12. However, this unpublished case is so bereft of analysis as to be unhelpful. *Thurston* is a two-paragraph opinion that provides neither analysis of the statute nor any specifics regarding the underlying pleading at issue. *Id*. at 586. It neither offers any guidance as to how this Court should interpret a complaint. It is not cited by a single court, and more importantly, unpublished. Thus, it is neither binding precedent nor authoritative. Fifth Cir. R. 47.5. It is hardly a trump card for Abbott.

On the other hand, it would be entirely consistent with *Ackermann* and any plain reading of the statute to make summary dispositive conclusions once the evidentiary facts are all marshaled via discovery. The Court would then be in the best position to address the applicability *vel non* of § 82.007, to this case. If then, as in *Lofton,* the Court finds (a) that the statute applies, and (b) that there is no evidence to rebut the statutory presumption, then at that time summary judgment might

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[8] Although the pharmaceutical industry would undoubtable welcome such a judicial interpretation of the statute, any such application would run afoul of legislative intent and be error. More, *anon*.

[9] Although Fn. 12 makes references to cases construing § 82.003, those cases are unavailing as this specific subsection of Chapter 82 has a different legislative intent, and on its face, has nothing to do with pharmaceutical manufacturers. Further, neither is a case concerning Rule 12(b)(6).

[10] Both *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 682 F. Supp. 2d 662, 675 (N.D. Tex. 2010) and *Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767 (S.D. Tex. 2008) are summary judgment cases.

be appropriate. But Abbott's reliance on § 82.007 for dismissal purposes at the pleadings stage is entirely without basis in law or in fact. The Court should deny Abbott's motion and prohibit it from wielding the statute in a manner inconsistent with the clear language of the statute itself.

B. § 82.007 is Inapplicable Where the Label Does Not Contain the Most Current FDA-Approved Warnings. Setting aside for a moment the premature nature of any § 82.007 analysis in this case, on its face, the statute makes clear that whatever protections it may, or may not, afford a pharmaceutical manufacturer, such protections may be rebutted. Abbott readily acknowledges such. Abbott's Memo at 10. Abbott's conclusory arguments *vis-à-vis* the an exception miss the mark and overlook those pled facts alleging that the operative warning did *not* comply with the most current FDA warning information. Such an allegation would, of course, render § 82.007 inapplicable in this case.

The side effect at issue in this case is Humira induced leukemia in an 11-year old child. As made abundantly clear in ¶¶ 11-14 of Plaintiffs' Complaint, prior to the time CBA, a minor, was ever prescribed Humira, pharmacovigilence[11] data indicated that children were at increased risk of developing cancers, including leukemia, who were using Humira.[12] The FDA specifically stated that "healthcare providers, parents, and caregivers" *should be* aware of this risk. *Id*. at 11. Abbott has,

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[11] Pharmacovigilence has been described as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.

[12] Abbott has argued it to be appropriate, and has asked the Court, to take judicial notice of "official FDA documents" that are publicly available. *See* Abbott's Memo at Fn. 2. To that end, the Court is equally free to take judicial notice of the FDA's June 4, 2008 communication discussed in Plaintiffs' Complaint. It is available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm070725.htm. The subsequent **BLACK BOX WARNING** concerning these lethal side effects that is equally discussed and referenced in Plaintiffs' Complaint is available at http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalproducts/ucm175843.htm. We respectfully ask the Court to take judicial notice of both.

and had, a statutory duty to not only perform adequate pharmacovigilence, but also to warn "as soon as" a reasonable association of a safety related side effect appears. *Id.; see also* 21 C.F.R. § 201.80 (e)("The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."). By waiting nearly 17 months after this FDA directive, and then only doing so because of FDA mandate, Abbott breached its duty to patients. Complaint at ¶¶ 11-14, 18, 22-24.

Thus, at the time CBA, a minor, was prescribed Humira, Abbott's prescribing information was inadequate and did not comply with the FDA's risk information. In fact, the label did not even mention the word leukemia. Plaintiffs have articulated these facts and plead them as such. Taken as true, it is utterly plausible that Abbott has failed to do that which it is legally required to do. And failed to do so in such as manner as to render § 82.007 moot in this case. Given these allegations, under any fair reading of Rule 12(b)(6) or *Twombly/Iqbal*, Abbott's motion should be denied.

C. Plaintiffs' Have Sufficiently Pled an Exception to § 82.007. Although Plaintiffs believe that it is improper to afford any drug manufacturer § 82.007 protection without benefit of an evidentiary record, even should the Court disagree, the Court may also deny Abbott's motion because Plaintiffs' have alleged an exception to the statute.

The Complaint specifically alleges that Abbott possessed and/or otherwise knew about information reflecting an increased risk of cancers and leukemia in children and that this information, once in the possession of the FDA, triggered a **BLACK BOX WARNING** about this very risk. Complaint at ¶¶ 1, 11-14, 18. Abbott will not, and cannot, deny that it has a duty to monitor adverse events associated with its drugs. As the Court can readily see, and as referenced in the Complaint, *id*., the FDA had to ask Abbott to provide it with the child/cancer data. *See* FDA communication at Fn. 7. Thus, it did not possess important safety information that Abbott

possessed. Once the FDA analyzed the data, it mandated **BLACK BOX WARNINGS** with respect to this very risk in patients like CBA, a minor. This clearly indicates that Abbott withheld from or otherwise misrepresented to the FDA required information concerning a lethal side effect. Such allegations clearly trigger § 82.007(b)(1) and an exception to the statute.

To be candid, Plaintiffs do not specifically articulate § 82.007(b)(1) in the body of their Complaint. However, there is no formal requirement that Plaintiffs use some magic language or buzzwords in the body of the Complaint to satisfy either Rule 12(b)(6) or *Twombly/Iqbal*. Even *Thurston* imposes no such requirement. *Thurston* simply states, "...unless the plaintiff can satisfy one of five enumerated exceptions, *id.* § 82.007(b). Thurston's complaint does not plead facts sufficient to meet any of the exceptions." 415 Fed. App'x. at 586. Clearly, if taken as true, the facts chronicled above and directly alleged in Plaintiffs Complaint satisfy "one of five enumerated exceptions."

Additionally, the undersigned was lead counsel for the Plaintiff in *Ackermann*. If anyone is aware of the pitfalls of § 82.007 and burdens imposed on a Plaintiff under the statute, it is he. An § 82.007 defense was very much anticipated and Plaintiffs' Complaint was plead with both an invalidation of the statute and an exception in mind. The alleged facts make that clear. However, despite Abbott's indirect assertions to the contrary, there is no duty to divulge this type of work product.

Finally, Abbott argues in Fn. 7 of its Memo that this Court should take no note of the subsequent **BLACK BOX** label change for Humira. They summarily argue that Rule of Evidence 407 will preclude such. Yet, the allegations in the Complaint very much put Abbott's actions with respect to these label changes at issue. Paragraphs 11-14 and 18 clearly allege that Abbott waited to disseminate warnings specific to pediatric leukemais both before CBA, a minor, was prescribed

Humira and after. Such conduct, if taken as true as this Court is required to do for purposes of this Response, state a plausible claim for not only personal injury damages, but punitive damages as well. Abbott's self-serving comment is a nonstarter. The **BLACK BOX WARNING** is very much at issue in this case.

Plaintiffs' averments are specific, factual content, that when taken as true all provide abundant inference for a claim for relief. There is nothing speculative about the law nor Abbott's duty to adequately monitor and warn about the risks posed by the use of its prescription drug. The Court need not strain to find any inferences nor must it accept any conclusory legal allegations to comply with *Twombly/Iqbal* in this case. By alleging that Abbott failed to warn as required by both a "reasonable association" and FDA directive, Plaintiff's have plead sufficient facts to trigger an exception to § 82.007. Thereby, Abbott's motion should be denied.

D. Abbott's Warnings were Inadequate. Abbott further argues that its Humira warnings were adequate as a matter of law. Although it principally relies upon statutory protection for its conclusory statement, Abbott does call the Court's attention to the language contained in the package insert that it believes was "adequate." And it does so on multiple occasions. There is considerable dispute as to whether Abbott's proffered warnings are actually adequate as a matter of law.

As a threshold matter, under Texas law, the question of the adequacy of a warning is a question of fact to be determined by the jury. *Alm v. Aluminum Co. Of America*, 717 S.W.2d 588, 591-92 (Tex. 1986). Thus, the Court would have to ignore this bedrock principle of Texas jurisprudence to find the adequacy of Abbott's warnings a basis for granting a motion to dismiss. Nevertheless, with respect to the warning, the following is noteworthy.

A critical review of the included package insert materials on pages 5-6 and 9-10 of Abbott's Memo all reveal the following:

> "...the studies precludes the ability to draw firm conclusions...these malignancies in HUMIRA-treated and control-treated patients were similar in type and number to what would be expected in the general population...the potential role of TNF blocking therapy in the development of malignancies is not known...other infrequent serious adverse reactions [in] rheumatoid arthritis patients treated with Humira were..."

Lacking from this so called "adequate warning" was any mention of studies in any patient population of similar age or disease state to CBA, a minor.[13] Nor was there any mention whatsoever of leukemia, much less pediatric leukemia. On the other hand, the warning clearly distances itself from any potential link to malignancies, *i.e.,* no "firm conclusions," "[same as] would be expected in the general population," "[role] not known," etc. Thus, it is very much disputed that a set of warnings that not only does *not* mention the very illness that is being complained about, but also does *not* mention or otherwise concern the specific patient population and illness at issue, and is replete with caveats and denials, is truly adequate. Moreover, the fact that Abbott did not warn about pediatric leukemia until 17 months after the FDA warning further illustrates the *inadequacy* of this warning with respect to pediatric leukemia at the relevant time. Complaint at ¶¶ 11-14, 18.

Abbott made similar such arguments in the *Wendall* case, *supra*. Therein, like the case at bar, it argued that because the label described some "specific" risk of malignancies in certain patient populations, that it was sufficient to warn with respect to all patients who might be prescribed Humira. The Court found the argument unavailing:

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[13] CBA, a minor, was not a rheumatoid arthritis patient. As this case progresses, the importance of this distinction will become clear to the Court. Rheumatoid arthritis patients are, generally speaking, in and of themselves, at more risk of lymphoma. Thus, a warning as to a rheumatoid arthritis patient population would be meaningless when treating CBA, a minor. However, there is no need to further burden the Court with a "science discussion" at this juncture.

> "Abbott Labs argues that the pre-February, 2007 warnings were adequate because they sufficiently warned physicians of the risk of lymphoma in the context of taking Humira to treat rheumatoid arthritis. This argument misses the mark. Warnings concerning the use of Humira to treat rheumatoid arthritis cannot necessarily be read to warn against the use of the drug to treat Crohn's disease."

Wendell, 2010 WL 2465456 at 5. And in the same fashion, this Court should not accept such conditioned and ambiguous language to be "adequate" as a matter of law.

Finally, some further mention should be made of *Lofton,* 682 F. Supp. 2d 662 and *Ebel,* 536 F. Supp. 2d 767. Abbott cites these cases as support for its dismissal arguments. And while it is true that, after ample discovery, summary judgment was granted at least in part under § 82.007, it was equally granted under summary judgment principles and only after Plaintiffs were afforded the opportunity to fully develop the record. These post-discovery summary judgment cases have absolutely no bearing on Rule 12(b)(6) and offer no insight into the appropriate legal standard for dismissal at the inception of a case.

E. If § 82.007(b) is Preempted, So, Too, is § 82.007(a). Although this legal issue is lurking in the case, the Court need not grapple with it extensively at this juncture to deny the motion to dismiss. However, in a nutshell, here is the issue.

Because § 82.007 is a defensive statutory presumption, there is no requirement for a plaintiff to anticipate and negate it in her Complaint. However, once the evidence is developed during discovery, Plaintiffs expects that, in addition to the foregoing arguments, they will be able to further detail how Abbott has withheld evidence from the FDA, within the ambit of § 82.007(b)(1).

Drug companies usually argue, as Abbott has done here in a footnote, that subsection (b)(1) is preempted by *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001) and its progeny.[14]

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[14] *Yocham v. Novartis Pharm. Corp.*, 736 F. Supp. 2d 875, 891-92 (D.N.J. 2010) is an interesting citation for Abbott. This New Jersey case was ostensibly cited elsewhere to assist the

That will be a harder row to hoe now, in light of *Wyeth v. Levine*, 555 U.S. 555 (2009), but IF Abbott goes down that path, the response is that, IF (b)(1) is preempted, then so, too, is subsection (a), which creates the presumption in the first place. The inability to use the first-listed category of evidence to rebut the presumption necessarily expands the coverage of the presumption and thus, the scope of the immunity that the Texas legislature prescribed. In this circumstance, the exception is not severable from the rule, and section 82.007 is constitutionally invalid in its entirety.[15]

As the court noted in *Anderson v. Wood*, 137 Tex. 201, 152 S.W.2d 1084, 1087 (1941), "[w]hen part of a statute is unconstitutional, we sustain the remainder only if the result is consistent with the original legislative intent." It would be utterly inconsistent with legislative intent to sever (b)(1) from the statute and to do so would be contrary to judicial precedent, legislative intent, and would be error.

II. THE COMMON LAW "LEARNED INTERMEDIARY" AFFIRMATIVE DEFENSE DOES NOT WARRANT DISMISSAL OF A COMPLAINT.

It is curious that Abbott seeks preanswer, prediscovery dismissal of a claim via a, as of yet, unpled affirmative defense. In fact, with the exception of one case, *Wyeth-Ayerst Lab. Co. v. Medrano*, 28 S.W. 3d 87, 95 (Tex. Ct. App. 2000), every case cited by Abbott in this section of its

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Court in interpreting § 82.007. *See* Fn. 10 of Abbott's Memo. However, this case specifically *denied* summary judgment on plaintiff's failure to warn claim on the basis of the statute. And more specifically, in regard to the exception outlined in § 82.007(b)(1), the court stated as follows: "Defendant is not entitled to summary judgment with respect to Plaintiff's failure to-warn claim, because the exception to the statutory defense of FDA approval is not preempted by federal law..." *Id*.

[15] There is no specific severability clause in the legislation enacting section 82.007. But section 23.03 of the legislation containing Section 82.007(b) does set forth a standard by which to evaluate severability: a provision of the legislation is severable only if "[t]he invalidity does not affect other provisions or applications of the statute that can be given effect without the invalid provision or application . . ." Obviously, there is much, much more that can be said on the issue of preemption and severability, or the lack thereof, and although not ripe for discussion, should the Court desire further briefing, Plaintiffs would be more than able to accommodate the Court.

brief is a post-discovery, summary judgment case. *Medrano* is actually even later in the game as it is a directed verdict. Thus, they cite no case law supporting their "learned intermediary" pleading proposition. Nor could they, as they are, in essence, turning pleading requirements for this affirmative defense on its head.

Assuming for the moment that the learned intermediary doctrine without exception or caveat is even still the law in Texas, then the prescribing physician's testimony becomes relevant in this discussion. And continuing on in our hypothetical, premature discussion, perhaps, at the end of the day and close of discovery, Dr. Townsend will indeed have one day testified that 1) despite the operative Humira prescribing information not even mentioning pediatric leukemia as a side effect, 2) that despite Humira subsequently being given a **BLACK BOX WARNING** about pediatric leukemia, 3) that despite 11-year old CBA, a minor, contracting Humira induced leukemia, 4) that despite CBA, a minor, subsequently undergoing aggressive chemotherapy and radiation therapy, and 5) that despite CBA, a minor's life forever being changed, he would still prescribe Humira for a non-life threatening condition knowing what he knows now. Perhaps he would do so. But he has not done so. Nor is that day, today.

The last writing Texas court for present purposes is the Texas Court of Appeals' opinion in *Centocor, Inc. v. Hamilton,* 310 S.W.3d 476, 522 (Tex. App. 2010, pet. granted). The drug involved in that case is a biologic agent called "Remicade." It is one of the two major competitors of Abbott's Humira, at issue in this case. As other non-Texas courts have recently done, the *Centocor* court has called into question the viability of this "outdated and unpersuasive" doctrine in Texas.[16]

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[16] In addition to the *Perez* opinion from New Jersey, quoted by the *Centocor* court, which recognized a "mass media promotion" *exception* to the learned intermediary doctrine, the landmark case in this century is *State ex. rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 905 (2007) which rejected the doctrine in its entirety as being "outdated and unpersuasive." As the *Karl* court noted "the highest courts of the remaining twenty-two states, . . . have not adopted the learned

The *Centocor* court began its opinion with pithy observations about the differences between the real 21st Century world of direct-to-consumer advertising and the Marcus Welby era from whence the learned intermediary doctrine sprang in the first place:

> Our medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines. Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the "doctor knows best."
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> For good or ill, that has all changed. Medical services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy department of supermarkets and often paid for by third-party providers. Drug manufacturers now directly advertise products to consumers on the radio, television, the Internet, billboards on public transportation, and in magazines.

Centocor, 310 S.W.3d at 480, quoting *Perez v. Wyeth Labs*., 161 N.J. 1, 734 A.2d 1245, 1246–47 (1999).

Iqbal requires motions to dismiss to be determined from a "context specific" frame of reference. It is certainly true that some pharmaceutical cases have been lost by plaintiffs based on the learned intermediary doctrine. However, they have been lost on summary judgments, not dismissals. And some of those summary judgments have been reversed. *See e.g., McNeil v. Wyeth,* 462 F.3d 364 (5th Cir. 2006).

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intermediary doctrine.").

Joining West Virginia was New Mexico, where Federal District Judge Browning cited *Karl*, accepted its rationale, noted the incompatibility between this doctrine and strict tort liability, and predicted that the New Mexico Supreme Court would likewise reject it. *Rimbert v. Eli Lilly & Co.,* 577 F.Supp.2d 1174 (D.N.M. 2008); *see also Griffith v. Blatt*, 51 P.3d 1256 (Or. 2002)(rejecting doctrine for strict liability cases).

As interesting as the jurisprudential meandering may be, Abbott's specific complaints seem to be that Plaintiffs failed to plead any facts suggesting Humira's inadequate warning caused their injuries. It offers some contrived argument that Plaintiffs have some duty to plead the impact an additional warning would have had. Abbott's Memo at 13. Assuming *arguendo* that Texas learned intermediary law is unchanged, Abbott's argument is still contrary to such law.

Abbott cited the *Ebel* case as supportive precedent for its 82.007 arguments. However, *Ebel* eviscerates its arguments in this instance. Here is what *Ebel* says with respect to the learned intermediary doctrine, causation, and burdens:

> Defendant has the initial burden of proving that decedent received the medication through a physician with whom the decedent had a physician-patient relationship and that the warning Defendant provided to the prescribing physician was adequate. In the alternative, Defendant may escape liability with evidence that the prescribing physician was aware of all of the drug's risks that would have been mentioned in an adequate warning. Once Defendant meets its initial burden, Plaintiff must provide some evidence that Defendant's warning was inadequate or misleading.

Ebel, 536 F. Supp. 2d at 772-73. Thus, *it is Abbott*, not Plaintiffs, who bear the initial burden in this regard. Plaintiffs have no duty to negate anything until Abbott overcomes its burden. It has not done so. Nor has it cited any case that requires a specific allegation that Plaintiff's prescribing physician would "have not prescribed Humira but for his reliance..."

Moreover, even if the Court decides to undertake some type of Rule 12(b)(6) analysis, any fair examination of the allegations in Plaintiffs' Complaint will reveal that *Twombly/Iqbal* standards have been abundantly met. Paragraphs 22-24 each aver that Abbott's actions, or lack thereof, were either producing or proximate causes of Plaintiff's injuries, *i.e.,* "The specific acts of negligence include failure to warn, its misrepresentations, its overpromotion, and its negligent pharmacovigilence. Each was a proximate cause of CBA, a minor's [damages]." The specific

factual content was discussed previously and chronicled in ¶¶ 11-14, 18. This alone is more than enough to draw a reasonable plausible inference as to causative liability.

The bottom line at the present stage, however, is that dismissal is inappropriate. Although the well-pleaded facts of the Complaint do not have to anticipate and negate an affirmative defense like the learned intermediary doctrine, the facts set forth herein show plenty of reasons why it is premature and not properly before the Court at this time. Even if it was, Plaintiffs have appropriately pled their case. Accordingly, Abbott's motion should be denied in its entirety.

Conclusion

"Motions to dismiss under Rule 12(b)(6) are viewed with disfavor and are rarely granted." *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 232 (5th Cir. 2009). For the foregoing reasons, Abbott's Motion to Dismiss should be denied. However, and in the alternative, if for some reason the Court believes that Plaintiffs must specifically articulate § 82.007, the learned intermediary doctrine, and/or any specific exceptions to this statute within the body of their Complaint, then justice and fairness dictate that they be allowed to add this language. To that end, they respectfully request leave to do so via Amended Complaint.

Respectfully submitted,

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Certificate of Service

I certify that on this 1st day of November, 2011, Plaintiffs' Brief in Support of Response to Defendant's Motion to Dismiss Plaintiffs' Complaint has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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